JUN - 5 2000

K000767
Page 1 of 2

510(k) Summary

General Information

Classification	Class II
Trade Name	Memcath Urology Introducer Sheath
Submitter	Memcath Technologies LLC 1777 Oakdale Avenue West St. Paul, MN 55118-4031 651-450-7400
Contact	Marc Jaker Vice President

Intended Use

The Memcath Model 201 is intended to facilitate introduction of catheters or instruments into the urethra.

Predicate Devices

Memcath Urology Catheter, Model 101	K993226
MMG O'Neil Urinary Catheter Introducer	K884819

Device Description

The Memcath Model 201 is intended to facilitate introduction catheters or instruments into the urethra. The device consists of a PVC pusher tube with pre-loaded, self-deploying PTFE sheath membrane. This sheath system includes a polyurethane snap ring and nylon twist ring to secure the sheath to the pusher tube.

Materials

All materials used in the manufacture of the Memcath introducer sheath identical to the predicate Memcath Urological Intermittent catheter.

Testing

Products were tested for:

- Insertion/Withdrawal load
- Pull Test
- Body Tensile
- Tip Flex
- Sheath-to-Catheter Lubricity
- SAL
- EtO Residuals

All product testing met specifications

Summary of Substantial Equivalence

The Memcath urology introducer sheath is equivalent to the predicate products the Memcath Urology Catheter and MMG O'Neill Introducer Sheath. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent. Memcath Technologies believes the Model 201 is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2000

Mr. Marc Jaker
Vice President
Memcath Technologies, Inc.
1777 Oakdale Avenue
West St. Paul, MN 55118-4031

Re: K000767
Memcath Urology Introducer Sheath Model 201
Dated: March 8, 2000
Received: March 9, 2000
Regulatory Class: II
21 CFR §876.5130/Procode: 78 KNY

Dear Mr. Jaker:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

K000767

Indications for Use

510(k) Number (if known):	This application
Device Name:	Memcath Urology Introducer Sheath Model 201
Indications for Use:	The Memcath Model 201 Introducer Sheath is intended to facilitate the introduction of catheters or instruments into the urethra.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K 000767

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _
(Per 21 CFR 801.109) (Optional Format 1-2-96)